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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,752	12/08/2000	Gaines W. Hammond	BSC-181	4800
21323	7590	08/03/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP			PELLEGRINO, BRIAN E	
HIGH STREET TOWER			ART UNIT	PAPER NUMBER
125 HIGH STREET				3738
BOSTON, MA 02110			DATE MAILED: 08/03/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/733,752	HAMMOND ET AL. <i>On</i>
	Examiner	Art Unit
	Brian E Pellegrino	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 06 May 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 10-17 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-15 and 19-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the term "structure" for multiple elements is ambiguous. Additionally, there is no language to describe the relationship of the two so-called "structures" to even comprehend the scope of them.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25,26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 25 claims the "connecting segment .... extending through the external sphincter..", and is therefore positively claiming a living tissue. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable. The claim should include language such as "adapted to extend through" or "configured to extend through" etc.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10, 19,21,23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Devonec et al. (5876417). Devonec et al. disclose (Fig. 7) a stent body member **8** with a lumen therein and a connecting segment **7** releasably coupled to the distal end of the tubular element **8** via coupling means **14** in the form of a tubular body. It can be seen that the connecting segment **7** also includes a distal end **25** that is located outside the body. Devonec also discloses the tubular elements, which are connected together such that they are aligned to form the device from a single lumen, col. 2, lines 12-17. Devonec additionally discloses the body member has one or more side openings, col. 4, lines 24-26. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. The use of "substantially within" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, it can be construed that the body member is sized for placement "substantially within" the prostatic section of the urethra. With respect to claim 21, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Thus, the tubular body of Devonec (col. 4, lines 21,22) is "adapted to" fit within the lumens of the stent and connecting segments.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec et al. '417 in view of Nissenkorn (4973301). Devonec is explained above. However, Devonec does not disclose the urethral device having a retaining member that is expandable at the proximal end of the urethral device. Nissenkorn teaches (Fig. 4) an expandable member at the proximal end of the prostatic device to hold the device within the bladder and prostatic section of the urethra. It would have been obvious to one of ordinary skill in the art to use a proximal retaining member extending from the stent body as taught by Nissenkorn incorporated in the urethral device of Devonec et al. such that it does not get displaced during the surgical procedure. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the structure is capable of receiving a pushing device since it is hollow.

Claims 13-15,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec et al. '417 in view of Nissenkorn '301 as applied to claim 12 above, and further in view of Klumb et al. (6238430). Devonec as modified by Nissenkorn is explained as before. However, Devonec in view of Nissenkorn do not disclose the use of a mechanism having a handle to control the pushing device. Klumb et al. teach (Fig. 1) a handle **10** with an opening **16** and a mechanism **14** attached to a pushing device that is received within the stent, col. 6, lines 2-7. It would have been obvious to one of

ordinary skill in the art to use a controlled mechanism as taught by Klumb et al. with the urethral device of Devonec as modified by Nissenkorn such that the pushing and delivering of the expandable component can be done in a controlled fashion without causing trauma to the patient via the channel within the stent and retaining member.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec et al. '417 in view of Tessmann et al. (5167614). Devonec et al. is explained above. However, Devonec does not disclose one or more protuberances to aid in retention of the stent within the prostatic section of the urethra. Tessmann et al. teach a stent (Figs. 2,8) with a plurality of protuberances **16, 316** respectively to anchor the stent within the walls of the urethra. It would have been obvious to one of ordinary skill in the art to incorporate protuberances as taught by Tessmann on the stent of Devonec such that it prevents any migration of the stent while in the patient and ensures proper function of the device.

### ***Response to Arguments***

Applicant's arguments filed 5/6/04 have been fully considered but they are not persuasive. In response to applicant's argument that Devonec does not disclose a device "sized for placement substantially within", please note that the recitation that an element is "sized for" is not a positive limitation but only requires the ability to so perform. Clearly, the Devonec device can be placed "substantially within" the urethra. The use of "substantially within" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Regarding

the comments about the structure of Nissenkorn not disclosing structure for receiving a pushing device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738  
Brian E. Pellegrino

*Brian E. Pellegrino*